REMARKS

The Present Invention

The present invention is directed to an isolated or purified nucleic acid which codes for an I_h ion channel or a part thereof, a nucleic acid complementary thereto, a nucleic acid that is at least 80% identical to the isolated or purified nucleic acid of SEQ ID NO 1, 2, 3, 4, 5 or 12, a nucleic acid that hybridizes under low stringency conditions with SEQ ID NO 1, 2, 3, 4, 5 and/or 12, a vector comprising an aforementioned nucleic acid, a host cell comprising the aforementioned vector, and a composition comprising an aforementioned nucleic acid.

Amendments to the Claims

Claims 4-11 and 19-46 have been canceled as directed to a nonelected invention. Claims 1 and 2 have been canceled and claims 3, 12, 14-16 and 18 have been amended so as to point out more particularly and claim more distinctly the subject matter of the present invention. The amendment of claim 3 is supported by the specification at page 6, third paragraph, whereas the amendments of claims 12 and 13 are supported by the specification at page 8, first paragraph, for example.

The Pending Claims

Claims 3 and 12-18 are currently pending. Claims 3 and 12-15 are directed to the isolated or purified nucleic acid, whereas claim 16 is directed to the vector, claim 17 is directed to the host cell comprising the vector, and claim 18 is directed to a composition comprising the isolated or purified nucleic acid and a carrier thereof.

Restriction Requirement

Applicants acknowledge the rejoining of claim 13 with group VII.

Claim of Priority

Applicants acknowledge the requirement for filing a certified copy of the German priority document under 35 U.S.C. § 119 (b). A copy is enclosed herewith.

Objection to Drawings

Applicants acknowledge the objection to the drawings. Correctly labeled drawings are enclosed herewith. In addition, the heading "Brief Description of the Figures" has been added

before the brief descriptions of the figures starting on page 10, and the description of Figures 4A and 4B have been separated on page 12 of the specification.

Sequence Rules Compliance

Sequence identification numbers have been inserted after the two sequences set forth at the top of page 7. A new Sequence Listing (paper and disk copies) including SEQ ID Nos.: 19 and 20 is enclosed herewith.

Objection to the Specification

Applicants acknowledge the objection to the specification. A substitute specification incorporating the amendments to the specification indicated above is submitted herewith.

Discussion of Rejection under 35 U.S.C. § 112, second paragraph

The Office has rejected claims 1-3 and 12-18 under Section 112, second paragraph, as indefinite. This rejection is believed to be moot for the reasons set forth below.

The Office contends that claim 1 is indefinite as it is allegedly unclear what is an I_h ion channel or part thereof. This rejection is believed to be moot in view of the cancellation of claim 1.

The Office further contends that claim 3 is indefinite as it is allegedly unclear what constitutes a part thereof. This rejection is believed to be moot in view of the amendment of claim 3 as supported by the specification at, for example, page 6, paragraph 3. Contrary to what is contended by the Office, paragraph 2 on page 6 does not refer to parts of nucleic acids but, rather, to parts of amino acid sequences.

The Office still further contends that claims 14 and 15 are indefinite as it is allegedly unclear what constitutes low stringency hybridization and high stringency hybridization. This rejection is believed to moot in view of the amendments to these claims as supported by the specification at, for example, page 5, last paragraph, and page 6, first paragraph.

In view of the aforementioned amendments, the rejection of claims 12, 13, and 16-18 as depending from an indefinite base claims is believed to be moot.

Accordingly, Applicants submit that the claims are definite. Therefore, Applicants request the withdrawal of this rejection.

Discussion of Rejection under 35 U.S.C. § 101 and § 112, first paragraph

The Office has rejected claims 1-3 and 12-18 (claims 1 and 2 having been canceled) under Section 101 as allegedly lacking a specific and substantial utility or a well-established utility, and under Section 112, first paragraph, for insufficiency of disclosure. These rejections are traversed for the reasons set forth below.

Applicants have indicated that the claimed nucleic acid sequences can be used in a screening or diagnostic method (see specification at, for example, pg. 1, 2nd para.). As indicated at, for example, page 8, fifth paragraph, through page 9, line 8, of the specification, the claimed nucleic acid sequences can be used to test the effect of substances on ion channels. The method can comprise producing homogeneous channel preparation, for example, by expression of the nucleic acid molecules in a suitable host, such as oocytes, mammalian cells, and the like, and testing substances on the channel preparations. By measuring channel activity under the action or in the absence of test substances, it can be determined which substances are suited for influencing the channels. Alternatively, as indicated at, for example, page 9, third and fourth full paragraphs, of the specification, the claimed nucleic acid sequences can be used to diagnose cardiovascular disorders by contacting a part of a claimed nucleic acid with nucleic acids isolated from a patient and detecting a signal so as to determine the presence and/or absence of an ion-channel nucleic acid sequence. Mutations in ion channels of the patient also can be detected in this manner.

Applicants have also indicated that the claimed nucleic acid sequences can be used for the treatment and/or prophylaxis of cardiovascular disorders, sleep disturbances, disturbances of consciousness, and pain (see specification at, for example, pg. 1, 3rd para., and page 9, last three lines). As indicated at, for example, page 10, lines 1-5, of the specification, the claimed nucleic acid sequences can be used to treat or recognize at an early stage a cardiovascular disorder due to faulty control of the sinus node, to recognize disturbances of consciousness due to malfunctioning corticothalamic neurons, and as gene therapy of a patient in which the channel is no longer operative.

Applicants submit that the above utilities are specific. As pointed out in M.P.E.P. § 2107.01 at page 2100-32, "[a] general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed. Contrast the situation where an applicant discloses a specific biological activity and reasonably correlates that activity to a disease condition. Assertions falling within the latter category are sufficient to identify a specific utility for the invention. "

Applicants also submit that the above utilities are substantial. As pointed out in M.P.E.P. § 2107.01 at page 2100-32, "[a] 'substantial utility' defines a 'real world' use. ...both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a 'substantial utility' define a 'real world' context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a 'real world' context of use in identifying potential candidates for preventive measures or further monitoring." The stated utilities do not fall under any of the five categories identified as insubstantial in M.P.E.P. § 2107.01 at page 2100-32.

Furthermore, Applicants submit that the above utilities are credible. Applicants have disclosed the functions and the biological significance of the I_h ion channel encoded by the claimed polynucleotide in the instant specification at, for example, page 5, paragraph 5, and indicate at page 17, lines 6-7 from the bottom, that the electrophysiological properties *unequivocally* identify the polypeptide encoded by the claimed nucleic acid sequence as a member of the I_h channel family. In this regard, Applicants further point out that "[a]n Applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement." (M.P.E.P. § 2107 (II)(B)(1)(ii)). Furthermore, the Office "must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement" (M.P.E.P. § 2107(II)(D)).

In view of the foregoing, Applicants respectfully submit that the above utilities are specific, substantial, and credible. Accordingly, Applicants request the withdrawal of the rejections under Section 101 and 112, first paragraph.

Conclusion

In view of the foregoing, Applicants submit that the instant application is in good and proper form for allowance, and request that the Office pass this application to issuance. If, in the opinion of the Office, a telephone conference would expedite prosecution of the application, the Office is invited to contact the undersigned attorney.

Respectfully submitted,

Carol Larcher, Reg. No. 35,243
One of the Attorneys for Applicants
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
Chicago, Illinois 60601-6780
(312) 616-5600 (telephone)
(312) 616-5700 (facsimile)

Date: February 27, 2003

CERTIFICATE OF MAILING

I hereby certify that this AMENDMENT AND RESPONSE TO OFFICE ACTION (along with any documents referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Box Sequence, U.S. Patent and Trademark Office, P.O. Box 2327, Arlington, VA 22202.

Date: 2-27-03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Baumann et al.

Application No. 09/640,582

Art Unit: 1646

Examiner: N. S. Basi

Filed: August 17, 2000

For: SEQUENCES OF AN I_H ION CHANNEL AND USE THEREOF

AMENDMENTS TO THE SPECIFICATION AND CLAIMS IN RESPONSE TO OFFICE ACTION DATED AUGUST 27, 2002
(brackets indicate deletions; underlines indicate insertions)

Amendments to page 7, lines 1-2:

TWALFKALSHMLCIGYGKFPPQS [SEQ ID NO: 19]

PDAFWWAVVTMTTVGYGDMTPVG [SEQ ID NO: 20]

Amendments to the paragraph beginning at page 10, lines 14-15:

[The invention shall now be described with reference to the examples and the attached figures, of which:] BRIEF DESCRIPTION OF THE FIGURES

Amendments to the paragraph beginning at page 12, lines 12-13:

[Figures 4A and 4B show the blockade of the SPIH channels by Cs^+ (Figure 4A control, Figures 4B + 10 nM Cs^+] Figure 4A shows the blockade of the SPIH channels by Cs^+ (control).

Figure 4B shows the blockade of the SPIH channels by 10 mM Cs^+.

Amendments to existing claims:

Claims 1, 2, 4-11 and 19-46 have been cancelled.

3. (Amended) [The]An isolated or purified nucleic acid [of claim 2, characterized in that the nucleic acid comprises the sequence according to] comprising the nucleotide sequence of SEQ ID NO: 1 or a fragment thereof of at least six nucleotides [or a part thereof].

12. (Twice Amended) [The] An isolated or purified nucleic acid [of claim 1,] characterized in that the sequence thereof is at least 80% identical to the isolated or purified nucleic acid of SEQ ID NO: 1, 2, 3, 4, 5 or 12.

13. (Amended) The isolated or purified nucleic acid of claim 12, characterized in that the sequence thereof is at least 90% identical to the isolated or purified nucleic acid of SEQ ID NO. 1, 2, 3, 4, 5 or 12.

14. (Twice Amended) [The] An isolated or purified nucleic acid [of claim 1,] characterized in that the nucleic acid hybridizes under low stringency conditions with SEQ ID NO: 1, 2, 3, 4, 5 and/or 12, wherein said low stringency conditions include hybridization with 0.1-5 x SSC at 50-60° C.

15. (Amended) The isolated or purified nucleic acid of claim 14, characterized in that the nucleic acid hybridizes under stringent conditions with SEQ ID NO: 1, 2, 3, 4, 5 and/or 12, wherein said stringent conditions include hybridization with 0.1-5 x SSC at 60-70°C.

16. (Amended) A vector comprising the isolated or purified nucleic acid of claim [1] 3.

18. (Amended) A composition comprising the isolated or purified nucleic acid of claim [1] 3 and a carrier therefor.

PATENT
Attorney Docket No. 205970

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Baumann et al.

Application No. 09/640,582

Art Unit: 1646

Examiner: N. S. Basi

Filed: August 17, 2000

For: SEQUENCES OF AN I_H ION CHANNEL AND USE THEREOF

PENDING CLAIMS AFTER AMENDMENTS IN RESPONSE TO OFFICE ACTION DATED AUGUST 27, 2002

3. An isolated or purified nucleic acid comprising the nucleotide sequence of SEQ ID NO: 1 or a fragment thereof of at least six nucleotides.

12. An isolated or purified nucleic acid characterized in that the sequence thereof is at least 80% identical to the isolated or purified nucleic acid of SEQ ID NO 1, 2, 3, 4, 5 or 12.

13. The isolated or purified nucleic acid of claim 12, characterized in that the sequence thereof is at least 90% identical to the isolated or purified nucleic acid of SEQ ID NO 1, 2, 3, 4, 5 or 12.

14. An isolated or purified nucleic acid characterized in that the nucleic acid hybridizes under low stringency conditions with SEQ ID NO: 1, 2, 3, 4, 5 and/or 12, wherein said low stringency conditions include hybridization with 0.1-5 x SSC at 50-60° C.

15. The isolated or purified nucleic acid of claim 14, characterized in that the nucleic acid hybridizes under stringent conditions with SEQ ID NO: 1, 2, 3, 4, 5 and/or 12, wherein said stringent conditions include hybridization with 0.1-5 x SSC at 60-70°C.

16. A vector comprising the isolated or purified nucleic acid of claim 3.

17. A host cell comprising the vector of claim 16.

18. A composition comprising the isolated or purified nucleic acid of claim 3 and a carrier therefor.